UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SCIELE PHARMA, INC. and SCIELE PHARMA CAYMAN LTD.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 07-00664 (GMS)
MYLAN PHARMACEUTICALS, INC. and MYLAN LABORATORIES, INC.,	)	ORAL ARGUMENT REQUESTED
Defendants.	)	

MEMORANDUM IN SUPPORT OF DEFENDANT MYLAN'S RULE 12(b)(1) MOTION TO DISMISS PLAINTIFF SCIELE'S COMPLAINT FOR LACK OF STANDING AND SUBJECT MATTER JURISDICTION

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REGULATIONS

Defendants Mylan Pharmaceuticals, Inc. ("Mylan Pharms") and Mylan Laboratories, Inc. (now known as Mylan Inc.) (collectively "Mylan") respectfully submit this memorandum in support of their Rule 12(b)(1), Fed. R. Civ. P., motion to dismiss the Complaint of Plaintiffs Sciele Pharma, Inc. and Sciele Pharma Cayman Ltd. (collectively "Sciele") for lack of standing and subject matter jurisdiction.

INTRODUCTION

Mylan Pharms has filed an abbreviated new drug application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to market a non-infringing generic nisoldipine drug product to compete with Sciele's brand product, Sular®—a prescription medication used to treat hypertension. To delay approval of Mylan Pharm's competing generic drug, Sciele filed this action for alleged infringement of U.S. Patent No. 4,892,741 ("the '741 patent"). Because Sciele lacks standing to bring this suit in its own name, the Court should dismiss this action for lack of subject matter jurisdiction.

Sciele does not now own—and indeed has never owned or otherwise held legal title to—the '741 patent. Rather, an unrelated German company, Bayer, is and remains the sole and exclusive "patentee" or owner of the '741 patent. Bayer is not a party to this action and has not asserted the '741 patent against Mylan. It is well settled that only the patentee that holds actual legal title to the patent may sue for infringement in its own name. A mere licensee, even an exclusive one, may not sue in its own name unless it holds *all* substantial rights in the patent, such that it is, in effect, the assignee and patentee.

Here, Sciele concedes, as it must, that it does not own or hold legal title to the '741 patent. Sciele nonetheless asserts, without foundation, that it is the "exclusive licensee with all substantial rights" in the patent. But the Distributorship Agreement between Bayer and Sciele says otherwise. While Bayer may have appointed Sciele to be the exclusive distributor of Sular®

in the United States under the '741 patent, Bayer remains the sole and exclusive owner. Bayer has also retained other substantial rights in the '741 patent, including the right and obligation to enforce the patent in the first instance; the right and obligation to maintain the patent in full force and effect in the United States, including seeking any extensions thereof; and the exclusive manufacturing rights under the patent. Sciele, on the other hand, has no exclusive right to enforce the '741 patent unless and until Bayer declines to do so. Nor does Sciele have the right to manufacture the patented product, or to have it manufactured by anyone else, but rather must purchase all of its requirements from Bayer. In fact, Bayer's covenant not to sue Sciele and its customers applies if, and only if, Sciele obtains the patented product manufactured by Bayer or its designee. And in view of Sciele's obligation to purchase only patented product manufactured by Bayer (or its designee), Bayer also retains a substantial economic interest in the patent. All told, Sciele does not—by any stretch of the imagination—possess all substantial rights in the '741 patent, and thus cannot, as a matter of law, be considered the assignee and patentee.

Accordingly, Sciele has no standing to sue for infringement of the '741 patent in its own name. The Court, therefore, should and indeed must dismiss this action for lack of subject matter jurisdiction.

BACKGROUND

This action arises under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act.[1] Congress enacted Hatch-Waxman for the express purpose of "get[ting] generic drugs into the hands of patients at reasonable prices—fast." *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991). To achieve that goal, Hatch-Waxman created the ANDA

[1] Hatch-Waxman formally is known as the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271).

procedure and "a mechanism to facilitate the adjudication of claims of infringement of patents relating to the innovator's drugs" before the generic drug has been marketed. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358 (Fed. Cir. 2003).

I. Statutory And Regulatory Framework.

In order to obtain FDA approval to sell a drug that has not been previously approved, a company generally must file a new drug application ("NDA"). *See* 21 U.S.C. § 355 (b)(1) and (b)(2). In addition to safety and efficacy information, an NDA applicant must file with FDA the number and expiration date of any patent that claims "the drug" or a method of using "the drug" for which the applicant submitted the application. 21 U.S.C. § 355(b)(1), (c)(2). FDA publishes this information in its publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." *See* 21 C.F.R. § 314.53(e).

A generic drug company may file an ANDA, as Mylan Pharms has done here, for FDA approval to market a generic version of a previously-approved NDA drug. An ANDA is "abbreviated" in that it substitutes bioequivalence data for the full studies of safety and efficacy found in an NDA. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990). An ANDA also must contain one of four "certifications" for each patent that the NDA applicant has submitted for listing in the Orange Book. *See* 21 U.S.C. § 355(j)(2)(A)(vii). With certain exceptions not applicable here, an ANDA applicant seeking approval to market a generic drug before expiration of a listed patent must submit a "paragraph IV certification" stating that the listed patent is invalid and/or will not be infringed by the generic drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The ANDA applicant must then notify the patentee and NDA-holder of the factual and legal bases for that certification. *See* 21 U.S.C. § 355(j)(2)(B).

The submission of an ANDA with a paragraph IV certification constitutes a "technical" or "highly artificial" act of infringement that creates the subject matter jurisdiction necessary for a district court to resolve any disputes regarding patent infringement or validity before the generic drug is actually sold. *See* 35 U.S.C. § 271(e)(2)(A) ("It shall be an act of infringement to submit an application under [21 U.S.C. § 355(j)] . . . if the purpose . . . is to obtain approval . . . before the expiration of such patent."); *Eli Lilly*, 496 U.S. at 678 (holding that 35 U.S.C. § 271(e)(2)(A) created "a highly artificial act of infringement that consists of submitting an ANDA" with a paragraph IV certification). The "very limited and technical purpose" of this "highly artificial act" is to permit suit to be brought despite the fact that generic companies have not yet infringed the patents at issue. *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1351 (Fed. Cir. 2004).

If the patent owner files such a suit within 45 days of receiving notice of the ANDA and paragraph IV certification, FDA approval of the ANDA is automatically stayed—regardless of the suit's merit or lack thereof—until the earlier of 30 months or a judicial determination that the patent is invalid and/or not infringed. *See* 21 U.S.C. § 355(j)(5)(B)(iii). In exchange for this automatic 30-month stay of approval of the competing generic drug, Congress imposed an express statutory duty on all parties to "reasonably cooperate in expediting the action." 21 U.S.C. § 355(j)(5)(B)(iii). Congress empowered the district court, among other things, to shorten the 30-month stay if the brand company breaches this duty. *See id.*

II. Statement Of Facts.

Mylan Pharms has submitted an ANDA seeking FDA approval to manufacture, market and sell nisoldipine extended-release tablets, 40 mg. (*See* D.I. 1, Compl. ¶ 28). Mylan Pharms' ANDA contains a paragraph IV certification to the only Orange Book-listed patent for

Sular®: the '741 patent assigned to, and owned by, Bayer. (*See id.* ¶¶ 17-18 and Rakoczy Decl. Ex. A, '741 patent at cover page). [2] As required by statute and regulation, Mylan Pharms provided Bayer, the patent owner, and Sciele, the purported NDA-holder for Sular®, with the requisite notice of its paragraph IV ANDA filing, including the factual and legal basis for its certification of non-infringement. (*See id.* ¶¶ 17-19). In response, on October 22, 2007, Sciele—but not Bayer—filed this action against Mylan alleging infringement of the '741 patent under 35 U.S.C. § 271(e)(2)(A). (*See* D.I. 1, Compl.).

A. Bayer—And Only Bayer—Is The Patentee That Holds Legal Title To The '741 Patent.

Bayer, not Sciele, researched and developed the extended-release nisoldipine tablets that are currently sold in the United States under the brand-name Sular®. (*See, e.g.,* Rakoczy Decl. Ex. B, February 13, 2002 Press Release entitled "First Horizon Announces Agreement to Acquire the Antihypertensive Drug Sular – nisoldipine – From AstraZeneca," at p. 1 of 4 ("Sular was developed and patented by Bayer AG and was approved by the Food and Drug Administration in 1995.")). On or about June 8, 1988, Bayer filed the first U.S. patent application for this purported invention. (*See id.* Ex. A, '741 patent at cover page). On or about January 9, 1990, the U.S. Patent and Trademark Office ("PTO") issued the '741 patent —which purports to cover and claim Sular®—to named inventors Andreas Ohm, Helmut Luchtenberg, Shinji Maegata and Wolfgang Opitz, all of Germany. (*See id.*). As issued, the '741 patent is assigned on its face to Bayer AG. (*See id.*). According to the PTO's electronic on-line assignment database, on or about March 7, 2005, Bayer AG assigned the '741 patent to one of its affiliates, Bayer Healthcare AG. (*See id.* Ex. C, 3-7-05 Assignment). For convenience and ease

[2] All references to "Rakoczy Decl." are to the Declaration of William A. Rakoczy, Esq., submitted concurrently herewith.

of reference, we refer to both affiliates, Bayer AG and Bayer Healthcare AG, collectively as "Bayer." To date, Bayer remains the sole and exclusive owner of the '741 patent.

B. Bayer Retains Substantial Rights In The '741 Patent.

On or about December 12, 2001, Bayer entered into a Distributorship Agreement with Sciele (then known as "First Horizon Pharmaceutical Corporation") for Sular® in the United States. (*See* Rakoczy Decl. Ex. D, 12-12-01 Distributorship Agreement). Under that Agreement, Bayer appointed Sciele the exclusive distributor of Sular® in the United States. (*See id.* art. 2.1 ("BAYER hereby appoints [Sciele] exclusively to have [Sular®] packaged and to sell and distribute [Sular®] in the TERRITORY under the provisions, terms and conditions stipulated in this AGREEMENT and with the reservations made hereinafter.")). In connection with that appointment as distributor, Bayer granted Sciele the exclusive right and license to "promote, sell and distribute" Sular® under the '741 patent. (*See id.* art. 2.2 ("BAYER hereby grants to [Sciele] the exclusive right and license, including the right to grant sublicenses, in the TERRITORY, to use, have used, package, and have packaged, sell, and have sold [Sular®] under the ['741 patent] . . . .")). Bayer also agreed not to enforce the '741 patent against Sciele or its customers for the "marketing and sale" of Sular®, but only if Sciele markets, sells and distributes product manufactured by Bayer or its designee. (*See id.* art. 16.1).

In fact, the exclusive distributorship license granted by Bayer is expressly limited to the distribution and sale of Sular® under the '741 patent. Bayer did not grant Sciele any right or license whatsoever to manufacture Sular® under the '741 patent.[3] Rather, Bayer retained all

[3] Even Sciele has acknowledged in public SEC filings that it only received a license under the '741 patent to sell and distribute Sular®, *not* to manufacture it: "We entered into a ten year agreement with Bayer, which appoints us as the exclusive party to sell and distribute Sular in the United States, provides us with the rights to sell Sular under certain patents and other technical information owned by Bayer, and provides for the manufacture and supply of Sular to us." (Rakoczy Decl. Ex. E, 3-28-02 Form 10-K at 7).

rights under the '741 patent to manufacture and supply Sular® to Sciele. (*See* Rakoczy Decl. Ex. D, 12-12-01 Distributorship Agreement art. 6.2 ("[Sular®] shall be manufactured, stored and shipped by BAYER . . . ."); art. 7.1 ("BAYER, agrees to manufacture and supply such quantities of [Sular®] as are specified . . . .")). Sciele, in turn, must purchase all of its Sular® requirements from Bayer, for which it pays Bayer a negotiated price. (*See id.* art. 6.1 ("[Sciele] shall purchase from BAYER and BAYER shall sell to [Sciele, Sciele's] requirements according to [Sciele's] orders of [Sular®].")). Bayer's license and covenant not to sue, in turn, apply only if Sciele sells patented product manufactured and supplied by Bayer under the '741 patent. Thus, to date, Bayer remains the exclusive manufacturer of Sular® under the '741 patent in the United States. To that end, Bayer retains the right to license others to manufacture Sular® under the '741 patent. (*See id.* art. 6.3 ("[I]n the case where BAYER selects a third party to manufacture, analyze or store [Sular®] . . . .")).

The Distributorship Agreement also makes clear that Bayer remains the sole and exclusive owner of the '741 patent: "BAYER is and shall be, subject to the provisions of this Agreement, the sole and exclusive owner of the ['741 patent] . . . and no other person or entity, other than [Sciele] as herein provided, has or shall have any claim of ownership with respect to the ['741 patent]." (Rakoczy Decl. Ex. D, 12-12-01 Distributorship Agreement art. 15.5.1(III)). With that exclusive ownership, Bayer also retained the obligation and right to enforce the '741 patent against potential infringers in the first instance:

> [Sciele] and BAYER shall each give the other PARTY immediate notice in writing of any known or presumed counterfeits or imitations or infringements upon the ['741 patent], and of any infringements by third parties of the benefits accruing to [Sciele] from them. [Sciele] will afford BAYER full cooperation for the protection of the ['741 patent]. ***In the event that BAYER learns of any known or presumed counterfeits or imitations or infringements through such notice from [Sciele] or otherwise,***

> ***BAYER at BAYER's cost shall promptly take such appropriate steps as are determined by BAYER to be necessary in order to protect the interests of the PARTIES hereunder and the benefits accruing to the PARTIES hereunder, provided, however, the institution, prosecution and completion of any and all measures, actions and procedures with respect to alleged infringers of the ['741 patent] are reserved exclusively for the decision of BAYER***, unless BAYER fails to take action to protect its rights to the ['741 patent] within 90 days after notice of any such infringement, in which event [Sciele] at [Sciele's] cost shall have the right to take such action as [Sciele] deems necessary to prevent any such infringement and recover any damages realized by or threatened to [Sciele] as a result of such infringement, and BAYER agrees to cooperate with and assist [Sciele] in its so doing.

(*Id.* art. 16.2 (emphasis added)). Thus, Bayer is obligated to, and "shall promptly," take action in the first instance to enforce the patent, and such decisions are reserved exclusively for Bayer. Sciele, on the other hand, has no independent right to enforce anything, unless Bayer fails to do so in the first instance. Bayer also maintains the right and obligation to maintain the '741 patent in full force and effect in the United States. (*See id.* art. 16.4).

NATURE AND STAGE OF PROCEEDINGS

This Hatch-Waxman patent case concerns the '741 patent, which expires on or about June 8, 2008. Sciele filed this action for alleged infringement on October 22, 2007. Mylan's stipulated time for response to the Complaint is December 18, 2007.

SUMMARY OF ARGUMENT

It is well settled that only the patentee which holds actual legal title to a patent may sue for infringement in its own name. A mere licensee, even an exclusive one, may not sue in its own name unless it holds *all* substantial rights in the patent—such that it is, in effect, the assignee and patentee. Here, Sciele holds neither legal title to the '741 patent, nor "*all* substantial rights" in the patent. Rather, Bayer remains the sole and exclusive patentee and owner of the '741 patent. Sciele, on the other hand, is not even an exclusive licensee of all rights

in the patent, but rather only an exclusive distributor of the patented product. This alone should preclude standing. But even if Sciele were an exclusive licensee, the undisputed evidence of record also demonstrates that Bayer has retained substantial rights in the '741 patent, including, among others, the right and obligation to maintain the patent and seek extensions thereof; the right to develop and introduce new products under the patent; exclusive manufacturing rights under the patent; and the right and obligation to enforce the patent against potential infringers in the first instance. Because Sciele does not hold all substantial rights in the patent, it lacks standing to sue in its own name.

ARGUMENT

"The question of standing to sue is a jurisdictional one[.]" *Rite-Hite Corp. v. Kelly Co.*, 56 F.3d 1538, 1551 (Fed. Cir. 1995). Standing is a "threshold question in every federal case, determining the power of the court to entertain the suit." *Warth v. Seldin*, 422 U.S. 490, 498 (1975). Thus, "[f]ederal courts are under an independent obligation to examine their own jurisdiction, and standing 'is perhaps the most important of [the jurisdictional] doctrines.' " *Monsanto Co. v. Aventis Cropscience SA*, 226 F. Supp. 2d 531, 537 (D. Del. 2002)(quoting *FW/PBS Inc. v. City of Dallas*, 493 U.S. 215, 231 (1990)). "It is well settled that standing cannot be 'inferred argumentatively from averments in the pleadings,' but rather 'must affirmatively appear in the record[.]' " *Id.* at 538 (internal citation omitted)(quoting *Mansfield, C. & L.M.R. Co. v. Swan*, 111 U.S. 379, 382 (1884)). Sciele alone bears the burden of proving standing and jurisdiction. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992) ("The party invoking federal jurisdiction bears the burden of establishing [elements proving standing]."); *Ortho Pharm. Corp. v. Genetics Inst., Inc.*, 52 F.3d 1026, 1032-33 (Fed. Cir. 1995) ("The burden of demonstrating standing falls to [Plaintiff] . . . .").

Where, as here, Mylan challenges jurisdiction as a factual matter, this Court affords the allegations of the Complaint no presumption of truth. *See Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977). Instead, "the trial court is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case" and to consider evidence beyond the pleadings. *Id.*; *see also Turicentro, S.A. v. Am. Airlines Inc.*, 303 F.3d 293, 300 n.4 (3d Cir. 2002) ("[T]he court must weigh the evidence relating to jurisdiction, with discretion to allow affidavits, documents, and even limited evidentiary hearings . . . .").

I. A Licensee, Even An Exclusive One, That Does Not Possess *All* Substantial Rights In The Patent Lacks Standing To Sue In Its Own Name.

The rules of standing are well settled. Only a "patentee" may bring an action for patent infringement. *See* 35 U.S.C. § 281; *Textile Prods., Inc. v. Mead Corp.*, 134 F.3d 1481, 1483 (Fed. Cir. 1998). The "patentee" includes "not only the patentee to whom the patent was issued but also the successors in title to the patentee." 35 U.S.C. § 100(d); *see also Textile Prods.*, 134 F.3d at 1483-84; *Propat Int'l Corp. v. Rpost, Inc.*, 473 F.3d 1187, 1189 (Fed. Cir. 2007). The law therefore requires "that a suit for infringement of patent rights ordinarily be brought by a party holding legal title to the patent." *Propat*, 473 F.3d at 1189. But "[e]ven if the patentee does not transfer formal legal title, the patentee may effect a transfer of ownership for standing purposes if it conveys all substantial rights in the patent to the transferee." *Id.* "A grant of all substantial rights in a patent amounts to an assignment—that is, a transfer of title in the patent—which confers constitutional standing on the assignee to sue another for patent infringement in its own name." *Intellectual Prop. Dev., Inc. v. TCI Cablevision of Cal., Inc.*, 248 F.3d 1333, 1345 (Fed. Cir. 2001); *see also Abbott Labs. v. Diamedix Corp.*, 47 F.3d 1128, 1131 (Fed. Cir. 1995).

In certain limited circumstances, an exclusive licensee can sue in its own name if, and only if, it holds "all substantial rights" under the patent. *Textile Prods.*, 134 F.3d at 1484. But "an exclusive licensee that does not have all substantial rights has standing to sue third parties only as a co-plaintiff with the patentee." *Id.* Otherwise, the remedies provided in the patent statute are unavailable to the exclusive licensee. *Monsanto*, 226 F. Supp. 2d at 539. The reason why is simple—" 'to enable the alleged infringer to respond in one action to all claims of infringement for his act, and thus either to defeat all claims in one action, or by satisfying one adverse decree to bar all subsequent actions.' " *Abbott*, 47 F.3d at 1131 (quoting *Indep. Wireless Tel. Co. v. Radio Corp. of Am.*, 269 U.S. 459 (1926)).[4]

In view of these well-settled principles, Sciele has no standing to sue in its own name here, either as the patentee and holder of legal title to the '741 patent, or as an exclusive licensee with "all substantial rights" in the patent.

II. The Complaint Must Be Dismissed Because Sciele Lacks Standing To Sue In Its Own Name.

Here, of course, Sciele has sued Mylan for alleged infringement of the '741 patent solely in its own name. But Sciele is not the patentee or holder of legal title to the '741 patent. Nor is Sciele an exclusive licensee with "all substantial rights" in the '741 patent. As such, Sciele lacks standing to sue in its own name. The Court therefore should dismiss this action for lack of standing and subject matter jurisdiction.

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[4] Moreover, a bare, nonexclusive licensee has no standing under any circumstances and therefore has no right to sue for infringement, either independently or as a co-plaintiff with the patentee. *Textile Prods.*, 134 F.3d at 1484; *Kalman v. Berlyn Corp.*, 914 F.2d 1473, 1481 (Fed. Cir. 1990).

A. Sciele Is Not The Patentee And Does Not Hold Legal Title To The '741 Patent.

As an initial matter, no one can seriously dispute that Sciele is not the record owner or assignee of the '741 patent. According to the records of the PTO, Bayer remains the assignee, owner and successor in title to the '741 patent. (*See* Rakoczy Decl. Ex. C, 3-7-05 Assignment). And Sciele has not suggested otherwise. The Distributorship Agreement also expressly provides that Bayer remains the "sole and exclusive owner of the ['741 patent]." (*Id.* Ex. D, 12-12-01 Distributorship Agreement art. 15.5.1(III)). In fact, not even Sciele appears to claim otherwise, but rather, at most, claims to be the "exclusive license." (D.I. 1, Compl. ¶ 14 (alleging that Sciele is the "exclusive licensee of the '741 patent . . . .")).

Accordingly, Sciele does not now hold, and in fact has never held, legal title to the '741 patent. Sciele therefore lacks constitutional standing to sue in its own name as the "patentee." *See* 35 U.S.C. § 100(d); *Textile Prods.*, 134 F.3d at 1483-84.

B. Because Bayer Indisputably Retains Substantial Rights In The '741 Patent, Sciele Is Not An "Exclusive Licensee" With "All Substantial Rights" Under The Patent, And Therefore Lacks Standing To Sue In Its Own Name.

"Because it is undisputed that [Bayer] is the party with legal title to the patent, [Sciele] is entitled to sue in its own name alone, without [Bayer's] participation, only if [Bayer] has transferred to [Sciele] all substantial rights in the patent." *Propat*, 473 F.3d at 1189. As an initial matter, it bears emphasizing that Sciele does *not* even have an exclusive license to all of the material patent rights. As noted, Sciele is licensed as an exclusive distributor only, with no rights at all to manufacture the patented product, or to preclude Bayer from having someone else make the patented product. In addition, Sciele's exclusive distributor rights extend only to Sular®, and no other embodiments of the '741 patent, without the prior approval of Bayer. (*See* Rakoczy Decl. Ex. D, 12-12-01 Distributorship Agreement art. 3.1). All of this, of course,

makes Sciele a bare licensee with no standing to sue with or without Bayer. *See Textile Prods.*, 134 F.3d at 1484 ("Thus, if a patentee-licensor is free to grant licenses to others, licensees under that patent are not exclusive licensees."); *Kalman,* 914 F.2d at 1481 (holding that bare or nonexclusive licensee has no standing under any circumstances, with or without the patentee). For that reason alone, the Court should dismiss this action for lack of standing.

But even if Sciele were an "exclusive licensee," it must still prove that it holds ***all***—repeat ***all***—substantial rights in the '741 patent. But this, Sciele cannot do. "To determine whether an agreement constitutes just an exclusive license or instead also transfers 'all substantial rights' in a patent, [the Court] must ascertain the intention of the parties and examine the substance of what was granted by the agreement." *Mentor H/S, Inc. v. Med. Device Alliance*, 240 F.3d 1016, 1017 (Fed. Cir. 2001). Here, even a cursory review of the Distributorship Agreement confirms beyond a shadow of a doubt that Bayer has retained significant and substantial rights in the '741 patent. We briefly address just a few of them below.

First, the Distributorship Agreement expressly provides that Bayer is, and will continue to be, the "sole and exclusive owner" of the '741 patent. (*See* Rakoczy Decl. Ex. D, 12-12-01 Distributorship Agreement art. 15.5.1(III) ("BAYER is and shall be . . . the sole and exclusive owner of the ['741 patent] . . . ."). The Agreement further requires and obligates Bayer to maintain the '741 patent in full force and effect in the United States, and even grants Bayer the right to seek extensions thereof. (*See id.* art. 16.4). The Federal Circuit has recognized that the responsibility to maintain a patent is "an indication that the party with that obligation has retained an ownership interest in the patent." *Propat*, 473 F.3d at 1191; *see also Mentor*, 240 F.3d at 1018.

Second, Bayer retains the right to develop and introduce new nisoldipine products under the '741 patent. (*See* Rakoczy Decl. Ex. D, 12-12-01 Distributorship Agreement art. 11.1 ("If, during the term of this AGREEMENT, BAYER plans to introduce inside or outside the TERRITORY a new form of products which contains Nisoldipine . . . ."). While Sciele may have a right of first refusal on such new nisoldipine products, under certain circumstances, Bayer is free to offer such product to others. (*See id.*). So Sciele cannot even preclude the sale of competing nisoldipine products in all circumstances. This, too, is an indication that Bayer has retained significant ownership rights in the '741 patent. *See Mentor*, 240 F.3d at 1018 (noting that patentee's ability to develop and manufacture products (for sale only to the licensee) was an indication that the patentee retained a significant ownership interest in the patent).

Third, and as already noted above, Bayer retains the exclusive right to manufacture and supply the patented product. (*See* Rakoczy Decl. Ex. D, 12-12-01 Distributorship Agreement art. 6.2 ("[Sular®] shall be manufactured, stored and shipped by BAYER . . . ."); art. 7.1 ("BAYER, agrees to manufacture and supply such quantities of [Sular®] as are specified . . . .")). Sciele has no right to manufacture anything under the patent, but rather must purchase all of its requirements from Bayer, or a third-party manufacturer designated by Bayer. (*See id.* art. 6.1 ("[Sciele] shall purchase from BAYER and BAYER shall sell to [Sciele, Sciele's] requirements according to [Sciele's] orders of [Sular®]."); art. 6.3 ("[I]n the case where Bayer selects a third-party to manufacture . . . [Sular®] . . . .")). Indeed, Bayer has only covenanted not to sue Sciele and its customers for the marketing and sale of the patented products that are manufactured and supplied by Bayer or its designee. (*See id.* art. 16.1). To the extent Sciele attempted to market, sell or distribute a patented product made by Sciele or anyone else, Bayer could sue Sciele for infringement. This alone confirms that the parties never

intended a transfer of all substantial rights in the patent, but rather only a limited exclusive distributorship, with all manufacturing rights under the patent remaining with Bayer. Bayer therefore "retains an economic interest in the patent and a substantial measure of control over decisions affecting patent rights." *See Propat*, 473 F.3d at 1191.

Fourth, and perhaps most importantly, Bayer has the right and indeed obligation to sue potential infringers in the first instance. The Agreement expressly obligates Bayer, and only Bayer, to "***promptly take such appropriate steps as are determined by BAYER to be necessary in order to protect the interests of the PARTIES . . . .***" (*See* Rakoczy Decl. Ex. D, 12-12-01 Distributorship Agreement art. 16.2 (emphasis added)). The Agreement further provides that "***the institution, prosecution and completion of any and all measures, actions and procedures with respect to alleged infringers of the ['741 patent] are reserved exclusively for the decision of BAYER . . . .***" (*Id.* (emphasis added)). With that right, Bayer obviously retains the ability to seek damages or other relief from potential infringers. In contrast, Sciele has no independent and unfettered right to enforce the patent, but rather can do so if, and only if, Bayer fails to do so. Sciele cannot seriously contend that it possesses all substantial rights in the patent where, as here, Bayer retains the right and obligation to pursue infringers in the first instance.

All told, these are precisely the circumstances that the Federal Circuit has held do not evidence a transfer of all substantial rights in the patent. In *Mentor*, for example, as in this case, the patentee retained the right to manufacture the product and to develop other products under the patent (for sale to the licensee); the patentee was obliged to maintain the patent; and the patentee had the first right and obligation to sue parties for infringement. *See Mentor*, 240 F.3d at 1018. The Federal Circuit concluded that "in light of [the patentee's] substantial retained rights, particularly its initial right and obligation to sue for infringement, we conclude that [the

licensee] did not receive all substantial rights in the patent." *Id.* ; *see also Procter & Gamble Co. v. Paragon Trade Brands, Inc.*, 917 F. Supp. 305, 307-11 (D. Del. 1995) (dismissing exclusive licensee's patent infringement counterclaim for lack of standing for failure to include actual patent owner); *Monsanto*, 226 F. Supp. 2d at 539-40 (partially dismissing action for lack of standing because licensees did not own "all substantial rights" in the patent).

So, too, here. It cannot be said, under any reasonable interpretation of the Distributorship Agreement, that Bayer has transferred all substantial rights in the patent to Sciele. Thus, even if Sciele were an exclusive licensee, it does not possess all substantial rights in the patent and therefore is not a patentee with standing to sue in its own name.

CONCLUSION

Sciele neither holds legal title to, nor all substantial rights in, the '741 patent. Sciele therefore lacks standing to sue in its own name. The Court therefore should dismiss Sciele's Complaint for lack of subject matter jurisdiction.

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